

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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CX 4/80.2

CL 2001/18 – FBT  
May 2001

To: Codex Contact Points  
Interested International Organizations

From: Secretary, Joint FAO/WHO Food Standards Programme  
FAO, Viale delle Terme di Caracalla, 00100 Italy

Subject: **Request for submission of information on analytical methods for consideration by the *Ad Hoc* Working Group on Analytical Methods of the *Ad Hoc* Task Force on Foods Derived from Biotechnology**

Deadline: **31 July 2001**

Comments: **To:**  
Dr. Marianna Schauzu  
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Protection of Consumers  
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**Copy to:**  
Secretary, Joint FAO/WHO Food  
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FAO  
Viale delle Terme di Caracalla,  
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The Working Group on Analytical Methods held its first meeting on 23 March 2001 in Tokyo, Japan. A total of 41 delegates and representatives from 19 countries and 4 international organizations participated in the meeting.

The purpose of the meeting was to discuss the results of an inquiry which had been initiated with circular letter CL 2000/29-FBT/MAS. As a result of this inquiry a list of methods validated by inter-laboratory studies was presented to the Second Session of the *Ad Hoc* Task Force on Foods Derived from Biotechnology held in Chiba, Japan from 25 to 29 March 2001. This list has been amended and is attached to this letter (Annex 1).

On the basis of the recommendations of the Working Group on Analytical Methods, the Task Force agreed to document the present status of validation of the methods that had been reported by the member countries. It recommended that a register or depository containing relevant information on methods for the detection or identification of foods or food ingredients derived from biotechnology as well as the availability of reference materials be established. The Task Force agreed to prepare a Circular Letter requesting member countries and interested international organizations<sup>1</sup>:

1. to complement the existing list with documented information on further validated detection methods as well as extraction methods;

<sup>1</sup> ALINORM 01/34A, para. 86



2. to provide information on the criteria of validation as well as performance criteria and specificity of methods;
3. to comment on the status of publication of validated methods;
4. to provide opinions on the purpose of a register containing relevant information on methods suitable for the detection of modifications in foods or food ingredients derived from biotechnology and on criteria for their inclusion into a register;
5. to comment on the appropriate place(s) of a register;
6. to provide opinions on how the access to reference materials could be guaranteed.

Member countries and international organizations are kindly invited to provide information requested above, in accordance to the following instructions:

(A) In relation to **points 1 to 3** above (only those member countries and international organizations which had reported on validated methods)

- State how many laboratories had participated in the inter-laboratory study
- Provide, for validation of **qualitative detection methods**, any further information on the following criteria:
  - specificity
  - sensitivity/limit of detection (LOD)
  - false positive results
  - false negative results
- Provide, in addition for **quantitative detection methods**:
  - limit of quantification
  - precision
  - accuracy
- Provide any further documentation concerning performance criteria, status of validation and publication of validated methods.

(B) In relation to **points 1 to 3** above (all member countries and international organizations)

Provide documented information on additional validated detection methods as well as methods for the extraction of nucleic acids/proteins or other methods by using the reply form attached as Annex 2 to this circular letter. The electronic version of the reply form can be downloaded from the following Codex Website:

<ftp://ftp.fao.org/codex/ccfbt2/Wgmethods/>

(C) In relation to **points 4 to 6** above (all member countries and international organizations)

- Provide opinions on the purpose of a register containing relevant information on methods suitable for the detection of modifications in foods or food ingredients derived from biotechnology and on criteria for their inclusion into a register;
- Comment on the appropriate place(s) of a register;
- Provide opinions on how the access to reference materials could be guaranteed.

All information should be sent, preferably by e-mail or fax, by 31 July 2001 to Dr. Marianna Schauzu, BgVV, Postfach 33 00 13, D-14191 Berlin, Germany (Fax: +49-30-8412-3635; E-Mail: [m.schauzu@bgvv.de](mailto:m.schauzu@bgvv.de)) with a copy to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, I-00100 Rome, Italy (Fax: +39-06-5705-4593; E-mail: [codex@fao.org](mailto:codex@fao.org)). The information received will be compiled by the delegation of Germany for review by the Working Group at its next meeting which will presumably be held immediately prior to the next session of the Task Force in March 2002.